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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN, *ex rel.* DAVID KESTER, Plaintiffs and Relator, -against - NOVARTIS PHARMACEUTICALS CORPORATION, *et al.* Defendants.	Case No. 11-CIV-8196 (CM) **STATE OF WASHINGTON'S MEMORANDUM OF LAW IN SUPPORT OF SECOND MOTION TO AMEND COMPLAINT-IN-INTERVENTION**

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I. INTRODUCTION

Pursuant to Fed. R. Civ. P. 15(a)(2) and Fed. R. Civ. P. 24(b)(1)(B), the State of Washington (Washington) submits this second motion to amend the Complaint-in-Intervention (Complaint) filed by Washington in this action to add claims against Novartis as it relates to the Accredo Exjade transactions. .

The Plaintiff States, including Washington, previously intervened against Novartis, but only with respect to claims relating to kickbacks that Novartis offered and paid to one particular pharmacy, BioScrip, that distributed Exjade. As indicated in Washington's prior motion, it has learned that the scope of the alleged fraud was more extensive than realized. In addition, subsequent admissions made by Accredo Health Group, Inc. ("Accredo"), make it clear to Washington that Novartis offered unlawful inducements to Accredo as part of its efforts to promote sales of Exjade.

Justice supports allowing Washington to further intervene and vindicate the State's interest in this matter as to the Accredo related claims. Notably, Washington does not seek to bring new parties into the litigation, nor to sue over additional drugs, but merely to expand the scope of its claims against Novartis to include claims arising from its unlawful marketing efforts with Accredo. Washington is seeking to amend only as to one aspect of the Relator's Complaint and is not seeking to bring any new claims that do not already exist as to BioScrip. Moreover, by Order dated May 6, 2015 (Dkt. No. 425), this Court granted the United States the right to intervene as to these precise claims. Thus, allowing Washington to amend the complaint will not materially affect the scope of discovery or trial.

The Court has subject matter jurisdiction to entertain Washington's claims under 28 U.S.C. § 1331; 28 U.S.C. § 1345; 28 U.S.C. § 1367(a); and 31 U.S.C. § 3732(b) and should grant this motion.

II. PROCEDURAL BACKGROUND

As set forth in the Plaintiff States' Complaints-in-Intervention (Dkt. Nos. 60, 61, 257), relator David Kester filed his original complaint against Novartis and the specialty pharmacies on November 11, 2011, pursuant to the False Claims Act, 31 U.S.C. § 3729, *et seq*, and similar state statutes. The State of Washington is not a named party to relator's action.

On January 24, 2014, the Court granted Washington's unopposed motion to intervene and on January 27, 2014, Washington filed its Complaint-in-Intervention against Novartis as it relates to the Exjade transactions involving Novartis and BioScrip. (Dkt. Nos. 77 and 82) Importantly, all of the motions brought by Novartis as it relates to Washington's BioScrip claims, have, in large part, been denied. (Dkt. No. 234, *Novartis VI)*

On September 15, 2014, relator filed a Third Amended Complaint which does not raise claims on behalf of the State of Washington. (Dkt. No. 253 at ¶ 103). In January 2015, Washington sought to amend its complaint-in-intervention as to both Accredo and Novartis. Accredo opposed the motion; Novartis did not. On April 10, 2015, the Court denied Washington's motion (Dkt. No. 412, *Novartis VIII)*. The Court recognized that Novartis had not filed an opposition to Washington's motion. (*Id*. at pg 2)

III. MATERIAL EVIDENCE OF NOVARTIS DEALINGS WITH ACCREDO

After this action was unsealed in January 2014, the intervening States actively pursued discovery relating to the kickbacks that Novartis paid to BioScrip to promote sales of Exjade. Meanwhile, relator pursued discovery regarding his claims against Novartis and Accredo with

regard to the latter's role in the Exjade kickback scheme. Relator has taken interviews and depositions of former Accredo employees as well as obtained numerous documents regarding Accredo's participation in Novartis' scheme.

Relator's discovery efforts yielded new and important information concerning Novartis' relationship with Accredo, including the following examples:

- Beginning in late 2007, Novartis persistently pressured Accredo to increase its Exjade refill rate.
- Novartis had Accredo revamp how the latter's nurses dealt with Exjade patients, and Accredo's nurse call scripts directed nurses to tell patients that it was "very important" to take Exjade while omitting reference to the serious adverse effects associated with the drug.
- Accredo shipment goals for Exjade, which were conveyed to personnel making calls to Exjade patients, were based on targets set by Novartis.

Based on the additional evidence obtained by Relator, the other intervening States have determined that sufficient basis exists to intervene against Novartis with respect to its dealings with Accredo and have also filed a motion seeking the Court's permission to intervene. In addition, Accredo entered into settlement discussions with the Plaintiff States and relator for which it has agreed in principle to pay approximately $15 million to resolve the States' claims against it.[1] In its settlement stipulation with the United States, Accredo made significant factual admissions with respect to Novartis' inducements to get Accredo to more aggressively push sales of Exjade. Accredo has agreed to settle the Exjade related claims with the State of Washington in the amount of $44,991.

[1] This amount is in addition to $45 million that Accredo has agreed to pay to the federal government.

IV. ARGUMENT

The Court should permit Washington to amend the complaint under Fed. R. Civ. P. 15(a)(2) and allow Washington to bring claims against Novartis as it pertains to the Accredo/Novartis Exjade transactions.

Federal Rule of Civil Procedure 15(a)(2) provides that permission to amend a complaint should be freely given when just requires. If there is not "evidence of undue delay, bad faith or dilatory motive" by the moving party, "…the leave sought should, as the rules require, be 'freely given.'" *Fershtadt v. Verizon Communications, Inc.*, 262 F.R.D. 336, 337-338 (2009) citing *Foman v. Davis*, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962). This court has ruled that a moving party must show the absence of prejudice or bad faith. *Id.*, citing *Block v. First Blood Ass'n*, 988 F.2d 344, 350 (2d Cir. 1993). The court does not abuse its discretion to allow amendment where the moving party demonstrates "a compelling reason for the delay." *Id.*, citing *Evans v. Syracuse City Sch. Dist.*, 704 F.2d 44, 47 (2d Cir. 1983).

Washington recognizes that the Court previously determined that it acted with undue delay and without adequate explanation when it filed the first motion to amend the complaint. Unlike the prior motion, however, the court has subsequently found good cause to allow the U.S. to intervene almost a year and half after declining the claims as to Accredo and new factual admissions have been made by Accredo since the first motion. Washington's motion is timely made relating to the timing of these two significant events.

Washington has not acted in bad faith, nor does it have a dilatory motive. Compelling new evidence through factual admissions by Accredo and a settlement in principle now exist in this matter, and for which Washington did not have when it filed the first motion. The Defendants will also not be prejudiced. As the Court previously stated, "Factors relevant to a

showing of prejudice include 'whether the assertion of new claims would: (1) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction." *Novartis VIII,* citing *Zublake v. UBS Warburg LLC,* 231 F.R.D. 159, 161 (S.D.N.Y. 2005) (other citations omitted). Here, Novartis will not have to expend significant additional resources to conduct discovery and prepare for trial. There will be some additional claims data provide by Washington to Novartis relating to the Accredo claims, but that data has in large part already been provided as it relates to relators complaint for the federal share of Washington's Medicaid dollar. Washington will merely need to provide the amount of its state share of the Medicaid claims. This will amount to 49 claims and less than $75,000 in alleged single "damages." Moreover, Novartis has not sought to depose any Washington witnesses and it has not sought to bring any other substantive motions beyond the Fed. R. Civ. P. 9(b) and Fed. R. Civ. P. 12(b)(6) motions against Washington as it relates to the existing BioScrip claims. Therefore, if Novartis opposes this motion, it will not be prejudiced as to discovery or additional motions given that none have been brought as to the BioScrip claims. Arguably, all previous rulings relating Novartis's prior motions would also apply as to the Accredo claims.

Washington's claims arise from the same transactions that give rise to the claims already brought by the Relator – Novartis's use of an unlawful kickback scheme to increase utilization of Exjade, which caused BioScrip *and* Accredo and to submit false claims to the Washington Medicaid program. Accredo's employees will be witnesses in the main action and will be the same witnesses needed for Washington's case. Washington's witnesses will also be the same. The claims that Washington contends were fraudulent and not otherwise payable are the same

claims targeted by the U.S. and the relator in the Third Amended Complaint on behalf of the named states therein, but not Washington.

Washington's participation in the case will not result in wasted or duplicative effort or delay any aspect of the existing case. Washington's claims are based on the same facts and similar legal theories as the existing parties' claims and its participation in this case is not expected to increase the scope of discovery in any meaningful sense. Washington will continue to coordinate its discovery, motion practice, and trial preparation to ensure efficient litigation that will not unduly delay or complicate the case. Washington's claims will not inject collateral legal issues into the case.

Washington's participation in this case is also consistent with Fed. R. Civ. P. 24(b)(1)(B) which provides that the court may permit anyone to intervene who "has a claim or defense that shares with the main action a common question of law or fact" and with 31 U.S.C. § 3732(b), which expressly provides that related state claims may be brought in a federal false claim action. *See U.S. ex rel., LaCorte v. Merck & Co., Inc.*, 2004 WL 595074, at 7, 2004 U.S. Dist. LEXIS 4860, at 23-24 (holding that Louisiana should be allowed to intervene to assert state law claims because section 3732(b) provides court with jurisdiction); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 509 F. Supp. 2d 82, 93 (D. Mass. 2007) (finding that the legislative history of section 3732(b) reflects that "Congress intended the provision to enhance the options of the states rather than restrict them").

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V. CONCLUSION

For the reasons stated above, the State of Washington respectfully requests leave to Amend the Complaint-in-Intervention in order to add claims against Defendant Novartis for the Accredo/Novartis Exjade transactions.

Dated: Olympia, WA
June 1, 2015

Respectfully submitted,

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